4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-3012]

Teva Branded Pharmaceutical Products R and D, Inc., et al.; Withdrawal of Approval of 35 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 35 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 006536	Urecholine (bethanechol chloride) Injection, 5 milligram (mg) /milliliter (mL) Urecholine (bethanechol chloride) Tablets, 5 mg, 10 mg, 25 mg, and 50 mg	Teva Branded Pharmaceutical Products R and D, Inc., 145 Brandywine Pkwy., West Chester, PA 19380
NDA 011707	Opana (oxymorphone hydrochloride (HCl)) Injection, 1 mg/mL and 1.5 mg/mL	Endo Pharmaceuticals, Inc., 1400 Atwater Dr., Malvern, PA 19355
NDA 012209	Fluorouracil Injection, 500 mg/10 mL and 2.5 grams (g)/50 mL	Spectrum Pharmaceuticals, Inc., 157 Technology Dr., Irvine, CA 92618
NDA 016772	Resectisol in plastic container (mannitol) Solution for Irrigation, 5 g/100 mL	B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109-9341
NDA 017354	Loestrin Fe 1/20 (ethinyl estradiol and norethindrone acetate) Tablets, 0.02 mg/1 mg	Teva Branded Pharmaceutical Products R and D, Inc.
NDA 017355	Loestrin Fe 1.5/30 (ethinyl estradiol and norethindrone acetate) Tablets, 0.03 mg/1.5 mg)	Do.
NDA 017716	Ovcon-35 (ethinyl estradiol and norethindrone) 28-Day Tablets, 0.035 mg/0.4 mg	Warner Chilcott Co., LLC, c/o Warner Chilcott (U.S.) LLC, 100 Enterprise Dr., NJ 07866
NDA 017875	Loestrin 1.5/30 (ethinyl estradiol and norethindrone acetate) 21-Day Tablets, 0.03 mg/1.5 mg	Teva Branded Pharmaceutical Products R and D, Inc.
NDA 017876	Loestrin 1/20 (ethinyl estradiol and norethindrone acetate) 21-Day Tablets, 0.02 mg/1 mg	Do.
NDA 018127	Ovcon-35 (ethinyl estradiol and norethindrone) 21-Day Tablets, 0.035 mg/0.4 mg	Warner Chilcott Co., LLC, c/o Warner Chilcott (U.S.) LLC
NDA 018238	Micro-K (potassium chloride) Extended-release Capsules, 8 milliequivalents (mEQ) Micro-K 10 (potassium chloride) Extended-release Capsules, 10 mEQ	Nesher Pharmaceuticals USA, LLC, 13910 Saint Charles Rock Rd., Bridgeton, MO 63044
NDA 018405	Aygestin (norethindrone acetate) Tablets, 5 mg	Teva Branded Pharmaceutical Products R&D, Inc.
NDA 018603	Zovirax (acyclovir sodium) for Injection, equivalent to (EQ) 250 mg base/vial, EQ 500 mg base/vial, and EQ 1 g base/vial	GlaxoSmithKline LLC, 2929 Walnut St., Suite 1700, Philadelphia, PA 19104
NDA 018764	Metronidazole Tablets, 250 mg and 500 mg	Watson Laboratories, Inc., an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc., 400 Interpace Pkwy., Parsippany, NJ 07054
NDA 018796	Pilopine HS (pilocarpine HCl) Ophthalmic Gel, 4%	Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, TX 76134-2099

NDA 019211	Theophylline in Dextrose 5% in plastic containers, Injection, 4 mg/mL, 40 mg/100 mL, 80 mg/100 mL, 160 mg/100 mL, 200 mg/100 mL, 320 mg/100 mL, and 400 mg/100 mL	Hospira, Inc., 275 North Field Dr., Bldg. HI-3S, Lake Forest, IL 60045
NDA 019926	Hexalen (altretamine) Capsules, 50 mg	Eisai, Inc., 155 Tice Blvd., Woodcliff Lake, NJ 07611
NDA 020130	Estrostep Fe (ethinyl estradiol and norethindrone acetate) Tablets, (white triangle) Tablets, 0.02 mg ethinyl estradiol and 1 mg norethindrone acetate; (white square) Tablets, 0.03 mg ethinyl estradiol and 1 mg norethindrone acetate; (white round) Tablets, 0.035 mg ethinyl estradiol and 1 mg norethindrone acetate Estrostep 21 (ethinyl estradiol and norethindrone acetate) Tablets, (white triangle) Tablets, 0.02 mg ethinyl estradiol and 1 mg norethindrone acetate; (white square) Tablets, 0.03 mg ethinyl estradiol and 1 mg norethindrone acetate; and (white round) Tablets, 0.035 mg ethinyl estradiol and 1 mg norethindrone acetate	Allergan Pharmaceuticals International Ltd., c/o Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940
NDA 020667	Mirapex (pramipexole dihydrocholoride) Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 0.75 mg, 1 mg, 1.25 mg, and 1.5 mg	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877
NDA 020713	Mircette (ethinyl estradiol; desogestrel and ethinyl estradiol) Tablets, (yellow) Tablets, 0.01 mg ethinyl estradiol and (white) Tablets, 0.15 mg desogestrel and 0.02 mg ethinyl estradiol	Teva Branded Pharmaceutical Products R and D, Inc.
NDA 020903	Rebetol (ribavirin) Capsules, 200 mg Rebetol (ribavirin) Capsules, 200 mg (comarketed as Rebetron Combination Therapy with Interferon ALFA-2B, Recombinant (INTRON A))	Merck Sharp and Dohme Corp., a subsidiary of Merck & Co., Inc., 126 East Lincoln Ave., P.O. Box 2000, Rahway, NJ 07065
NDA 021200	Zelnorm (tegaserod maleate) Tablets, EQ 2 mg base and EQ 6 mg base	Alfasigma USA, Inc., 550 Hills Dr., Suite 110B, Bedminster, NJ 07921
NDA 021546	Rebetol (rivavirin) Oral Solution, 40 mg/mL	Merck Sharp and Dohme Corp., a subsidiary of Merck & Co., Inc.
NDA 021858	Boniva (ibandronate sodium) Injection, EQ 3 mg base/3 mL	Hoffmann La Roche Inc., c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080-4900
NDA 021871	Loestrin 24 Fe (ethinyl estradiol and norethindrone acetate tablets, 0.02 mg/1mg; and ferrous fumarate tablets, 75 mg)	Teva Branded Pharmaceutical Products R and D, Inc.

NDA 022266	Onsolis (fentanyl citrate) Buccal Film, EQ 0.2 mg base, EQ 0.4 mg base, EQ 0.6 mg base, EQ 0.8 mg base, and EQ 1.2 mg base	Adalvo Limited c/o Biotech Research Group, 3810 Gunn Highway, Tampa, FL 33618
NDA 022569	Lazanda (fentanyl citrate) Nasal Spray, EQ 0.1 mg base, EQ 0.3 mg base, and EQ 0.4 mg base	BTcP Pharma LLC, c/o West Therapeutic Development, LLC, 1033 Skokie Blvd., Suite 620, Northbrook, IL 60062
NDA 040024	Dexferrum (ferric oxyhydroxide) Injection, EQ 50 mg iron/mL	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967
NDA 202342	Esomeprazole Strontium Delayed-release Capsules, 24.65 mg and 49.3 mg	Belcher Pharmatech, LLC, 6911 Bryan Dairy Rd., Suite 220, Largo, FL 33777
NDA 202788	Subsys (fentanyl) Sublingual Spray, 0.1 mg, 0.2 mg, 0.4 mg, 0.6 mg, 0.8 mg, 1.2 mg, and 1.6 mg	BTcP Pharma LLC, c/o West Therapeutic Development, LLC
NDA 204325	Adzenys ER (amphetamine) Extended-release Oral Suspension, EQ 1.25 mg base/mL	Neos Therapeutics Brands, Inc., 2940 N. Highway 360, Suite 400, Grand Prairie, TX 75050
NDA 205637	Bunavail (buprenorphine HCl and naloxone HCl) Buccal Film, EQ 2.1 mg base/EQ 0.3 mg base, EQ 4.2 mg base/EQ 0.7 mg base, and EQ 6.3 mg base/EQ 1 mg base	BioDelivery Sciences International, Inc., 4131 Park Lake Ave., Raleigh, NC 27612
NDA 210045	Consensi (amlodipine besylate and celecoxib) Tablets, EQ 2.5 mg base/200 mg, EQ 5 mg base/200 mg, and EQ 10 mg base/200 mg	Purple Biotech LTD, 2520 Meridian Pkwy., Suite 200, Durham, NC 27713
NDA 211281	Pizensy (lactitol) Oral Solution, 10 g	Braintree Laboratories, Inc., 60 Columbian St. West, Braintree, MA 02184
NDA 212038	Adhansia XR (methylphenidate HCl) Extended-release Capsules, 25 mg, 35 mg, 45 mg, 55 mg, 70 mg, and 85 mg	Purdue Pharma L.P., One Stamford Forum, 201 Tresser Blvd., Stamford, CT 06901-3431

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: December 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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